

**Enlarged Board of Appeal EPO, 19 February 2010,
Abbott Respiratory – Dosage regime**



Abbott

A Promise for Life

PATENT LAW

Second medical indication need not be treatment of another disease

- there can be only one sensible way of construing the requirement underlying the specificity of the use, namely merely by contrast to the generic broad protection conferred by the first claimed medical application of a substance or composition, which is in principle not confined to a particular indication.

Reformulated the first question corresponds in fact to the following: Is a new use, deserving patent protection, of a per se known medicament, necessarily restricted to a disease not yet treated by said composition? This question was mainly although not unanimously answered in the negative by the Boards of Appeal under the old law, EPC 1973, provided the invention was claimed in the so-called Swiss-type format, adopted by the Enlarged Board of Appeal in its decision G 5/83. That decision of the Enlarged Board of Appeal had filled a gap in the legal provisions and allowed claims concerning a second therapeutic indication of a known product, although not specifying whether such a second use could be something else than the treatment of another disease.

5.10.2 Under the new law, EPC 2000, the lacuna in the old provisions which had been closed in a praetorian way by decision G 5/83 and the subsequent case law of the boards of appeal, no longer exists. Article 54(5) EPC now provides for patent protection of a known substance or composition for "any specific use" of the said product in a method of therapy provided this use is not comprised in the state of the art and is inventive.

5.10.3 The Enlarged Board comes to the conclusion that there can be only one sensible way of construing the requirement underlying the specificity of the use, namely merely by contrast to the generic broad protection conferred by the first claimed medical application of a substance or composition, which is in principle not confined to a particular indication. Thus, the new use within the meaning of Article 54(5) EPC need not be the treatment of another disease.

- This is confirmed by the preparatory documents, which normally witness the intention of the legislator and constitute an ancillary means of interpretation of dispositions of law at least when it comes to their ratio legis.
- The first sentence of Article 53(c) EPC, prohibiting patent protection of methods for treatment by therapy, is to be read and understood together with

the provisions of its second sentence and with those of Articles 54(4) and (5) EPC respectively so that far from being mutually exclusive they are complementary.

- By virtue of a legal fiction Article 54(4) and (5) EPC acknowledges the notional novelty of substances or compositions even when they are as such already comprised in the state of the art, provided they are claimed for a new use in a method which Article 53(c) EPC excludes as such from patent protection.

In such cases the notional novelty and following it the non-obviousness, if any, is not derived from the substance or composition as such but from the purpose the claimed substance or composition is related to, namely from its intended therapeutic use. Such use can be either a new indication stricto sensu (in the sense of a disease not yet treated by the claimed substance or composition), or one or more steps pertaining by their nature to a therapeutic method which may not be claimed as such. Article 54(5) EPC, however, refers to "any specific use" (emphasis added). On the basis of that wording in conjunction with the declared intention of the legislator to maintain the status quo of protection evolved in the case law of the boards of appeal under decision G 5/83, the Enlarged Board holds that said use cannot be ex officio limited to a new indication stricto sensu.

- Seamless fit between (i) a patentable method using a composition that is not a treatment by therapy and (ii) a non-patentable treatment by therapy method but the use of a composition for making a medicament for use in such a treatment by therapy that is patentable

Dosage regimes

- there is no reason to give to a feature consisting in a new dosage regime of a known medicament a different treatment than the one given to any other specific use acknowledged in case law

The term "dosage regime" may cover different acceptations that are normally reflected by corresponding features in the wording of the claim. However, the Enlarged Board of Appeal considers that there is no need to define the term more precisely here.

- The claimed definition of the dosage regime must not only be verbally different from what was described in the state of the art but also reflect a different technical teaching.

- Furthermore, assuming for the sake of argument that the claimed modalities of the dosage regime would only consist in a mere selection within the teaching of a broader prior disclosure in the state of the art, then novelty could only be acknowledged if the criteria developed in the jurisprudence of the boards of appeal with respect to selection inventions would be fulfilled. One typical issue in such kinds of cases is whether the dosage regime defined in the claim has been shown to provide a particular technical effect as compared with what was known in the state of the art.

Swiss type claims no longer necessary

- the old law did not contain any notional acknowledgement of novelty of a claim directed to a known product based on a feature relating to an intended further - therapeutic - use of that product
- The new provisions of Article 54(5) EPC were precisely intended to fill this lacuna. In respect of second and further medical indications the EPC now allows use-related product claims directed to the substance itself whereas under EPC 1973 decision G 5/83 allowed claims directed to the use of a substance for the manufacture of the drug for a therapeutic indication ("Swiss-type claims").

The question of dosage regimes has also been the object of decisions of courts of EPC Contracting States. In the United Kingdom, the Court of Appeal for England and Wales reached the same result as here (Decision of 21 May 2008 in re Actavis UK Limited v. Merck & Co. Inc., (2008) EWCA Civ. 444). In Switzerland, the Tribunal of Commerce of the Canton of Zurich ruled in the opposite direction (Decisions of 14 April 2009, AA 090075 and AA 090077). In Germany, the Federal Court of Justice had doubts with respect to a claim worded similarly to the one in suit here, but none with respect to a claim in which the substance used was prepared ("hergerichtet") for administration according to a given dosage regime (Decision of 19 December 2006, X ZR 236/01 "Carvedilol II", Reasons II.1 and III.1).

The patents underlying these decisions were under the ambit of the old law which did not contain any notional acknowledgement of novelty of a claim directed to a known product based on a feature relating to an intended further - therapeutic - use of that product. The new provisions of Article 54(5) EPC were precisely intended to fill this lacuna. 6.5 In respect of second and further medical indications the EPC now allows use-related product claims directed to the substance itself whereas under EPC 1973 decision G 5/83 allowed claims directed to the use of a substance for the manufacture of the drug for a therapeutic indication ("Swiss-type claims").

Freedom of medical practitioners to prescribe generics may be restricted

- If deemed necessary, the freedom of medical practitioners may be protected by other means on the national level

It appears that the rights conferred on the patentee by the claim category under Article 54(5) EPC are likely broader, and could, in particular, lead to possible restrictions on the freedom of medical practitioners to prescribe or administer generics. However, in view of the clear provisions of Articles 53 (c), second sentence, and 54(5) EPC and the intention of the legislator, the Enlarged Board has no power to broaden or reduce in a praetorian way the scope of these provisions. If deemed necessary, the freedom of medical practitioners may be protected by other means on the national level (see also **G 1/04**, points 6.1 and 6.3 of the Reasons).

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Enlarged Board of Appeal, 19 February 2010

(P. Messerli, J.-P. Seitz, P. Alting Van Geusau, B. Gunzel, U. Kinkeldey, S. Nathanael, B. Schachenmann)
Case Number: **G 0002/08**

DECISION of the Enlarged Board of Appeal of 19 February 2010

Appellant: (Applicant): Abbott Respiratory LLC, 100 Abbott Park Road, Abbott Park, Illinois 60064 (US)

Representative: Wallace, Sheila Jane, Marks & Clerk LLP, 90 Long Acre, London WC2E 9RA (GB)

Referring Decision: Interlocutory decision of the Technical Board of Appeal 3.3.02 dated 22 April 2008 in case T 1319/04.

Composition of the Board: Chairman: P. Messerli

Members: J.-P. Seitz, P. Alting Van Geusau, B. Gunzel, U. Kinkeldey, S. Nathanael, B. Schachenmann

Summary of Facts and Submissions

I. European patent application No. 94 306 847.8 originally filed by Kos Life Sciences, Inc., now Abbott Respiratory LLC, was refused by a decision of the Examining Division of 25 September 2003 on the grounds of lack of novelty under Articles 54(1) and (2) EPC 1973 and because it did not meet the requirements of Article 52 (4) EPC 1973.

This decision was based on a Claim 1 which reads as follows :

"1. The use of nicotinic acid or a compound metabolized to nicotinic acid by the body selected from a group consisting of d-glucitol hexanicotinate, aluminium nicotinate, nericinol, d,l-alpha-tocopheryl nicotinate and nicotinyl alcohol tartrate, for the manufacture of a sustained release medicament for **use in the treatment by oral administration once per day prior to sleep, of hyperlipidaemia** characterised in that the medicament does not comprise in admixture, 5-30% hydroxypropyl methylcellulose, 2-15% of a water soluble pharmaceutical binder, 2-20% of a hydrophobic component and 30-90% nicotinic acid." (emphasis added)

As set out in the decision under appeal, the Examining Division was of the opinion that the subject-matter of Claim 1 was anticipated by the disclosure in earlier documents, which contemplated the use of nicotinic acid for the manufacture of a sustained release medicament for use in the treatment of hyperlipidaemia by oral administration.

In that respect, the first instance, referring in particular to decisions T 317/95 and T 584/97, concluded that the feature of Claim 1 relating to a specific drug regime, i.e. **once per day prior to sleep**, reflected a medical activity excluded from patentability under Article 52(4) EPC 1973, which could not therefore be considered to represent a further medical indication from which novelty can be derived (points 27 and 28 of the Reasons).

I.1 The applicant lodged an appeal against this decision and defended his application before the Board of Appeal on the basis of the same Claim 1.

I.1.1 As this application was pending on 13 December 2007, the date on which the EPC 2000 entered into force, and no decision on the grant of the patent had yet been taken, the Board of Appeal in the decision dated 22 April 2008 decided that, by virtue of the Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Art. 7 of the Act revising the European Patent Convention of 29 November 2000, Article 1, No. 1 and 3, the application in suit fell to be considered under the provisions of Articles 53(c), 54(4) and (5) EPC 2000, and no longer under Articles 52(4) and 54(5) EPC 1973 which governed the case when the Examining Division reached its decision.

I.1.2 The Board of Appeal came to the conclusion that the question whether medicaments for use in methods for treatment by therapy, where the only feature likely to confer novelty on the claim is a dosage regime, are patentable under Articles 53(c) and 54(5) EPC 2000 is an important point of law (decision T 1319/04, OJ EPO 2009, 36). The following questions were referred to the Enlarged Board of Appeal for decision:

(1) Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness?

(2) If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?

(3) Are any special considerations applicable when interpreting and applying Articles 53(c) and 54(5) EPC 2000?

I.2 By communications of 20 May and 23 May 2008, respectively, the Enlarged Board of Appeal invited the President of the EPO and the appellant to comment in writing on the points of law referred to it by the Technical Board of Appeal. Having regard to Article 10(2) of its Rules of Procedure the Enlarged Board further decided to announce in the Official Journal of the EPO further provisions concerning statements by third parties on the points of law referred to it by the Technical Board of Appeal. The statements of the appellant can be summarised as follows:

II.1 The provisions of Article 53(c) EPC 2000 excluding the patentability of methods of treatment by therapy constitute an exception to the general principle according to which patents can be granted in all fields of technology; as such this exception must be interpreted narrowly. This principle has been followed by the case law of the Boards of Appeal.

II.2 The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), to which almost all Contracting States of the European Patent Convention are also parties, equally foresees in its Article 27(1) that patents shall be available for any inventions in all fields of technology and in its Article 27(3) that members may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

Therefore to be consistent with the wording of Article 27(1) of the TRIPS Agreement, which the revised EPC had to be brought in line with, the exclusions of patentability as set out in Article 53(c) EPC 2000 have to be construed narrowly.

II.3 This is also consistent with the provisions of the Vienna Convention on the Law of Treaties, which the Enlarged Board of Appeal already accepted to apply in case G 5/83, according to which a treaty shall first and foremost be interpreted in good faith.

II.4 The intention of the authors of the revised EPC was that, regarding new Articles 54(4) and (5) EPC 2000 "the case law evolved by the EPO Enlarged Board of Appeal should be enshrined in the Convention ... the aim of the Basic Proposal was to keep the legal status quo for medical uses" (see *Travaux Préparatoires* MR/24/00, No 139). And since the Enlarged Board of Appeal in decision G 5/83 expressly allowed claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, it established in that decision the patentability of second and further therapeutic uses of a known medicament in the broadest sense of the term.

II.5 The case law of the Boards of Appeal followed this principle in allowing claims not only directed to the treatment of another disease, but also drawing their novelty from a method of administration, a new class of patients, as well as from new dosage regimes (i.a. T 51/93; T 19/86; T 143/94; T 1020/03). In particular decision T 1020/03 provided a detailed and convincing analysis of decision G 5/83, and came to the conclusion that the "specified use" the Enlarged Board of Appeal required for allowing a second medical use was to be understood "merely by way of contrast to the unspecified therapy allowable in a claim for a first medical use, and not as imposing any special conditions that a further medical use had to fulfil". This reasoning in decision T 1020/03 is also consistent with the findings of the Enlarged Board of Appeal in case G 2/88, in particular with point 10.3 of the Reasons of said decision according to which "with respect to a claim to a new use of a known compound, such new use may reflect a newly discovered technical effect described in the patent" the attaining of which "should then be considered as a functional technical feature of the claim".

II.6 To summarise his line of argumentation and in respect of the two first questions the appellant maintained that:

- specified, new and inventive treatments by therapy of the same illness are patentable under the EPC 1973 according to decision G 5/83 even when the novel feature consists in a new dosage regime,

- under the wording of EPC 2000 different new and inventive treatments by therapy of the same illness are patentable even where the only novel feature of this treatment consists in a new dosage regime, - the intention of the authors of the revised EPC 2000 was to enshrine decision G 5/83 into the EPC,

- no intention to exclude such treatments can be found in the *Travaux Préparatoires* to the EPC 2000 even

where the only novel feature of the therapeutic treatment is a new dosage regime,

- the Vienna Convention as well as the TRIPS Agreement mandate such uses as being patentable,
- specified, new and inventive treatments by therapy of the same illness are patentable applying the reasoning of decision T 1020/03, which equally applies to the EPC 2000,
- public policy requires that such uses be patentable and no reasons exist to the contrary.

II.7 In view of the above the appellant then came to the conclusion that the two first referred questions have to be answered in the affirmative.

II.8 With respect to question 3 the appellant submitted that as stated in decision G 5/83 "the intention of Article 52 (4) (now 53 (c) EPC 2000) is only to free from restraint non-commercial and non-industrial medical and veterinary activities" and that this exclusion should not "go beyond its proper limits". Although the EPO has no jurisdiction on enforcement of patent rights, he invited the Enlarged Board of Appeal to consider that according to Article 30 of the TRIPS Agreement it is the task of the Contracting States to provide exceptions to the exclusive rights conferred by a patent. The appellant saw no need to answer question 3.

II.9 Further, in a reply to a communication by the Enlarged Board of Appeal, the appellant filed with letter dated 22 October 2009 a new main and two auxiliary requests.

III. In her comments the President of the EPO essentially brought forward the following arguments:

III.1 Under Article 53(c) EPC 2000 European patents may not be granted for methods for treatment by therapy or surgery of the human or animal body, neither may they be granted for diagnostic methods practiced on them. They may however be granted for medicinal products for use in such methods. Already under the EPC 1973, to compensate for this exclusion, substances and compositions although already known in the art could nonetheless as such be patented for their first new and inventive use in one of these methods. No express provision in the EPC 1973 allowed in contrast purpose-related product claims for second or further medical indications of known substances or compositions already used as medicines.

III.2 New Article 5 4 (5) EPC contains an express permission of purpose-related product claims provided the new and inventive use of the substance or composition already known as a medicine be specific. However, the EPC does not give any definition of the precise meaning of this requirement that could encompass a new illness to be treated as well as the very disease that was already the object of a prior application, in which case the novelty of the use could be drawn from another distinguishing feature (e.g. different subjects to be healed or different modes of administration of the substance).

III.3 Turning to the Travaux Préparatoires for the revised Convention, to which according to the Vienna Convention on the Law of Treaties recourse may be had, the clear intention of the legislator was to elimi-

nate any legal uncertainty on patentability of further medical uses of a known medicine and therefore unambiguously to permit their protection in form of purpose-related product claims. In this respect the case law evolved by the EPO Enlarged Board of Appeal should be enshrined in the Convention in order to keep the legal status quo for medical uses. Therefore, there is no indication that the legislator intended to change the EPO practice as hitherto established by the case law of the Boards of Appeal on patentable second medical indications.

III.4 In decision G 5/83 the Enlarged Board of Appeal, dealing with this question as well as with that of the appropriate claim format, expressly acknowledged the patentability of further specified medical uses of a known substance or composition provided that, contrary to the purpose-related product claim format authorised for the first medical use of the same substance by Article 5 4 (5) EPC 1973, the claim was worded as a use claim for the manufacture of a medicament for treatment of the new indication. Whereas the novelty of the first medical indication of a known substance or composition was to be derived from this first medical use, the novelty of a claim directed to the process that formed the subject matter of the so-called Swiss-type claims was to be derived by analogy from the new therapeutic application rather than from the process of manufacturing the medicament for the new treatment by therapy.

This notional concept of novelty could not be transposed and could only be applied to claims directed to the uses of substances or compositions intended for use in a method referred to in Article 5 2 (4) EPC 1973.

III.5 The Enlarged Board of Appeal did not at that time precisely define what could fall under the term of "specified new and inventive therapeutic application". In fact all cases leading to the then referrals were related to the treatment of different diseases by a substance or composition already known for of a first medical indication.

III.6 Implementing these principles the Boards of Appeal took the view that decision G 5/83 did not exclude that a second medical application could also be derived from distinguishing features other than the treatment of a different disease. By doing so they extended the concept the Enlarged Board had evolved to cases where the known medicament was used in the treatment of the same illness. A body of decisions was quoted in this respect mainly related to new groups of subjects treated, new modes or routes of administration of a known substance and new technical effects in the patient's body.

III.7 To summarise, the Boards did not question under the ruling of the old law that the notional novelty concept drawn from decision G 5/83 could also apply in cases where the new and inventive use of a known substance aimed at healing the same illness, this approach being followed so far by the other departments of the EPO.

III.8 Under the EPC 2000 the wording of Article 54(5) allows the maintenance of this established practice. A

narrow interpretation of the will of the legislator to have the case law of the Enlarged Board of Appeal enshrined in the EPC might well lead to answering the first question in the negative if one considers that the basis for these referrals were all related to claims directed to a different illness. But the fact remains that the authors of the revision also expressed their will to have the status quo maintained for medical uses while presumably aware of the case law of the Boards of Appeal when drafting the new text.

The understanding the Boards had under the EPC 1973 of the required "specified new and inventive therapeutic application" can be transposed to the "specific use" now required by Article 54(5) EPC 2000. It can thus be contended that both terms highlight the contrast to the generic use allowable in a claim to a first medical indication. In the light of these considerations, the President expressed her opinion that the first question could be answered in the affirmative. She also expressed her wish that the Enlarged Board of Appeal uses the opportunity the current referral presents to draw the line between the exclusion set out in Article 53(c) EPC 2000 and patentability in this field of technology.

III.9 In respect of the second question, the President argued that whichever meaning be given, according to the circumstances, to the phrase "dosage regime", excluding it from the ambit of the definition "specific use" would amount to giving the latter a restrictive meaning. However there seems to be no established case law under the EPC 1973 regarding patentability of Swiss-type claims directed to a second medical indication when the distinguishing feature is a mere dosage regime.

III.9.1 Some Boards considered such a feature exclusively to pertain to the skill of the medical practitioner, whose activities must remain unfettered. Other decisions considered that a mere dosage regime could not represent a distinguishing feature conferring novelty on a claim in which the medicament to be used and the method of its application and the patient group subject of said application are all disclosed in the state of the art.

III.9.2 Reference was also made to the positive view expressed in decision T 1020/03 and to the reasoning underlying its findings that a claim formulated in the Swiss-type format can be allowable "irrespective of the degree of detail given for the therapeutic use". The President noticed further that the Board in decision T 1020/03 also expressed the view that "for a use to be treated as new it must be confined to what is new, and not merely directed to any use of a physiological/pharmacological effect or mechanism which underlay a previous therapeutic use but where the effect or mechanism had not been identified as such."

III.9.3 The President then referred to the case law of the national courts and in particular to:

1.the decision of the Court of Appeal for England and Wales of 21 May 2008 in re Actavis UK Limited v Merck & Co. Inc. [EWCA Civ 444, Reasons 28 and seq],

2.the decision of the German Federal Court of Justice [BGH] of 19 December 2006, XZR 236/01 "Carvedilol II".

Under the EPC 2000 the reasons set out in decision T 1020/03 could be followed, and a claim formatted as a purpose-related product claim was similar to a Swiss-type claim and could thus avoid a conflict with the prohibition set forth in Article 53(c) EPC 2000. As regards the requirement of "specific use", the wording could cover (as the formulation "specified new and inventive therapeutic application" used in decision G 5/83) medical indications which differed from the prior art use merely in the dosage regime, as argued in decision T 1020/03. III.10 With respect to question 3, the President suggests i.a. that any interpretation of the EPC provisions which would amount to Article 53(c) EPC becoming completely or even partially obsolete would be at odds not only with the legislator's intention but also with the policy considerations leading to the decision to maintain this provision in substance.

IV . In response to the invitation by the Enlarged Board numerous submissions were made by third parties in form of amici curiae briefs. Points made therein included essentially the following:

IV.1 Relating to Question 1:

- A majority considered that this question should be answered in the affirmative since the wording of Article 54(5) EPC is clear and does not suggest that some specific uses should be treated any differently from others, all the more when one considers that Article 53(c) EPC is an exception to patentability that has to be interpreted narrowly on the one hand and that the intention of the legislator was obviously to confirm the case law evolved by the Enlarged Board of Appeal in decision G 5/83 which clearly did not intend to reduce a second indication of a known drug to the treatment of another disease on the other hand.

- Some others were of the opinion that decision G 5/83 should be construed narrowly and that therefore a novel indication of a known drug should mandatorily consist in the treatment of another disease than that previously treated by this known product, so that Question 1 was to be answered in the negative.

IV.2 Relating to Question 2:

- A majority considered that a new dosage regime of a known drug could fall under "specific use" , relying in particular on the case law following decision G 5/83 (e . g . : decision T 1020/03).

- Some others were of the opinion that the task of assessing the right dosage of a drug exclusively belongs to the physician whose freedom must take precedence over any other property right, all the more if one would consider that Article 53(c) EPC precisely intends to guarantee this freedom.

- One third party also drew the attention of the Enlarged Board to the fact that the scope of protection conferred by a use related product claim, now expressly allowed by EPC 2000, is likely to be broader than that conferred by a socalled Swiss-type claim, and that this could put a fetter on the physician's freedom unless new dosage regimes continue to have to be claimed in

the format of a Swiss-type claim, which category therefore deserves maintenance.

A communication of the Enlarged Board informed the appellant, sole party to the present proceedings, of the issues the Enlarged Board of Appeal wished to be dealt with during the oral proceedings. These were held on 5 November 2009. At the end of the debate and before its closing the appellant requested that the first two questions referred to the Enlarged Board be answered in the affirmative and that the third question be answered in the negative. He further requested that his main and auxiliary requests filed on 22 October 2009 be admitted into the proceedings.

The Chairman then closed the debate and announced that the decision would be given in writing.

Reasons for the decision

1. Admissibility of the referral

The Enlarged Board of Appeal considers that the questions raise important points of law. Although the referring Board of Appeal has already decided that Claim 1 under dispute is inventive, this normally implying that its subject-matter is also novel, the referral is admissible. Since the acknowledgement of novelty ultimately may depend on the answers given to the questions referred, the Enlarged Board interprets this finding as only meaning that the dosage regime included in the claim was not factually anticipated. Hence the answers to the referred questions are considered decisive for the case under appeal and therefore the referral fulfils the requirements of Article II2 (1) a) EPC.

1.2 The referral is admissible.

2. Applicable Law

The application in suit was filed on 19 September 1994 and is still pending. Therefore according to Article 1 No. 1 and 3 of the Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000 (OJ EPO 2007, 197), revised Articles 53 (c) , 54 (4) and (5) EPC apply to it since it was pending on 13 December 2007 when EPC 2000 entered into force.

Construction of the first question of the referral

The question reads: "Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a **different, new and inventive treatment by therapy** of the same illness?" (emphasis added)

However under the heading of **exceptions** to patentability Article 53(c) EPC prescribes *inter alia* that European patents shall not be granted in respect of "**methods for treatment** of the human body . . . by **therapy** . . ." (emphasis added) and that "this provision shall not apply to products, in particular substances or compositions, for use in any of these method" (i.e. products which are new per se). Consistently Articles 54(4) and (5)EPC under the heading of novelty reiterate the same express exception for the benefit of substances or compositions already known per se, (i.e. comprised in the state of the art) with the proviso for

second or further uses in any such method that they be specific.

3.2 Hence, as mentioned in point 1.1 above, the issues of importance are the construction of the provisions of Article 53(c) EPC together with those of Articles 54(4) and (5) EPC and the answer to the question whether there is any need to reconcile them.

4. Rules of interpretation of the international law

4.1 In respect of this need the EPC, although the European Patent Organisation is not a party to the Vienna Convention on the Law of Treaties concluded on 23 May 1969 (hereinafter Vienna Convention), has to be construed according to the principles set out in the said Convention. In fact the Enlarged Board in decision G 5/83 (points 1-6 of the Reasons) already acknowledged their applicability. The relevant Articles 31 and 32 of the Vienna Convention read:

Article 31 - General rule of interpretation

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.

2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:

(a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;

(b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.

3. There shall be taken into account, together with the context:

(a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;

(b) any subsequent practice in the application of the treaty which established the agreement of the parties regarding its interpretation;

(c) any relevant rules of international law applicable in the relations between the parties.

4. A special meaning shall be given to a term if it is established that the parties so intended.

Article 32 - Supplementary means of interpretation Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31:

(a) leaves the meaning ambiguous or obscure; or

(b) leads to a result which is manifestly absurd or unreasonable.

4.2 From the reading of the two articles taken together it follows that the provisions of a treaty (here the EPC) must first be construed according to the ordinary meaning of the terms in their context and in the light of its object and purpose, which means that the judge is not entitled to depart from clear provisions of law, this principle pertaining to the requirement of good faith.

From the wording of Article 32 of the Vienna Convention it can also be derived that preparatory documents are primarily to be drawn into consideration in order to confirm a meaning or to determine a meaning if the first and ordinary means of construction would lead to ambiguity or to an absurd result.

4.3 Reference is made in this respect by the present decision to decision G 1/07 of 15 February 2010, point 3.1 of the Reasons, of the Enlarged Board of Appeal in which these issues have been dealt with in detail.

5. Identification of the changes in the provisions of the EPC

Article 53(c) EPC

5.1 Article 52(4) EPC 1973 provided under the heading "patentable inventions" inter alia that:

"Methods for treatment of the human or animal body ... by therapy ... shall not be regarded as inventions which are susceptible of industrial application ...".

5.2 In an opinion dated 16 December 2005 in case G 1/04 (OJ EPO 2006, 334) in respect of a point of law referred by the President of the EPO the Enlarged Board of Appeal considered under points 3 and 4 of the Reasons the ratio legis of the aforesaid provision. The Enlarged Board of Appeal came to the conclusion that from Article 52 EPC 1973 seen in context, it followed that diagnostic methods (and therefore by analogy therapeutic methods) practised on the human or animal body referred to in Article 52(4) EPC 1973 were inventions within the meaning of Article 52(1) EPC 1973 and thus also of Article 57 EPC 1973, which were however, by means of a legal fiction, regarded as not susceptible of industrial application. The Enlarged Board of Appeal went on to consider that corroboration for such a construction was to be found in the preparatory documents to the EPC 1973 (Minutes of the Diplomatic Conference, Minutes of Main Committee I, document M/PR/I, point 24). The purpose of Article 52(4) EPC 1973 was to restrict the concept of industrial application in the field of medical and veterinary treatments and that article was therefore to be regarded as lex specialis which took precedence over Article 57 EPC 1973, reference being made to decision T 116/85, OJ EPO 1989, 13, point 3.5 of the Reasons.

5.3 Nevertheless at that time the Enlarged Board of Appeal was well aware of the revision of the EPC soon to enter into force and stated further that, whilst the legislator had chosen the legal fiction of lack of industrial applicability, the exclusion from patentability of the above-mentioned methods under Article 52(4) EPC 1973 seemed actually to be based on socio-ethical and public health considerations. In fact physicians should be free to take all actions they considered suitable to prevent or to cure a disease, and in this exercise they should remain uninhibited by patents. The Enlarged Board of Appeal in opinion G 1/04 did not in that respect expressly refer to decision G 5/83 although the ratio decidendi of this provision had already been dealt with in point 22 of the Reasons of the latter decision: "The intention of Article 52(4) EPC (1973), again as recognised by the (German) Federal Court of Justice, is

only to free from restraint non-commercial and non-industrial medical ... activities".

5.4 From Article 1, items 17 and 18 of the Act revising the EPC (cf. Special edition No. 4, OJ EPO 2001, 3) it results that Article 53 (c) EPC provides inter alia, under the heading "exceptions to patentability", that European patents shall not be granted in respect of methods for treatment of the human body by therapy, whereas existing Article 52(4) EPC 1973 was deleted without substitution. According to point 6 of the explanatory remarks concerning the "transitional provisions" (published in the same Special edition of the OJ EPO 2001, 134) the shifting of the former provisions of Article 52(4) EPC 1973 to new Article 53(c) EPC 2000 "is a purely editorial change" and "does not change the actual legal position".

5.5 The Enlarged Board of Appeal in opinion G 1/04, point 10, in fine, held that the motive for the change was the realisation that such methods were excluded from patentability for reasons of public health and that, consequently, to base the exception on lack of industrial applicability was no longer justified. The preparatory documents CA/PL 8/99; CA/PL PV9, points 32-34; CA/PL PV14, points 152 and 157-158; CA/100/00 pages 41-42; MR/2/00, pages 45-46; MR/24/00, page 71, bear testimony to the grounds moving the legislator to make the amendments. As summarized in the Special edition No. 4, OJ EPO 2007, 50:

"2. The exclusion of methods of treatment and diagnostic methods referred to in Article 52(4) EPC 1973 has been added to the two exceptions to patentability in Article 53(a) and (b) EPC. While these surgical or therapeutic methods constitute inventions, they have so far been excluded from patentability by the fiction of their lack of industrial applicability. It is undesirable to uphold this fiction since methods of treatment and diagnostic methods are excluded from patentability in the interests of public health. It is therefore preferable to include these inventions in the exceptions to patentability in order to group the three categories of exceptions to patentability together in Article 53 (a), (b) and (c) EPC. It should also be noted that Article 27(3)(a) of the TRIPS Agreement states that 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' may be excluded from patentability. It is thus appropriate to transfer Article 52 (4) EPC 1973 to a new Article 53 (c) EPC with the aim of bringing the EPC into line with the TRIPS Agreement."

5.6 Hence, although the general principle holds good that the human body is outside the commercial sphere, that does not necessarily imply that methods for treating the human body by therapy are not as such susceptible of industrial application.

Said methods remain nevertheless excluded from patent protection with the consequence that any method claim containing even a single step pertaining by nature to a treatment by therapy is not allowable. This is established case law, see e.g. decisions T 82/93, OJ EPO 1996, 274; T 820/92, OJ EPO 1995, 113; T 182/90, OJ

EPO 1994, 641. In this respect reference is again made to the decision G 1/07, loc.cit., points 3.2 et seq. of the Reasons, of the Enlarged Board of Appeal where this issue is also dealt with in detail.

5.7 The provisions of Article 53(c) EPC are clear and unambiguous, drawing a borderline between unallowable method claims directed to a therapeutic treatment on the one hand and allowable claims to products for use in such methods on the other hand. To extend the respective domains of the prohibition or the express permission appears to exceed the bounds of what is permissible for the Enlarged Board of Appeal by way of interpretation. De facto the two concepts of a method for treatment by therapy and of a product to be used in such a method are so close to each other, that there is a considerable risk of confusion between them unless each is confined to its own domain as allocated to it by the law. In this respect it would be improper to consider the second sentence of Article 53(c) EPC as a lex specialis to be interpreted narrowly, rather on the contrary it is appropriate to give both provisions the same weight, and draw the general conclusion that in respect of claims directed to therapy, method claims are absolutely forbidden in order to leave the physician free to act unfettered, whereas product claims are allowable provided their subject-matter be new and inventive.

Article 54 (4) EPC

5.8 As regards new Article 54(4) EPC which corresponds to the former Article 54(5) EPC 1973, no fundamental change was intended. These provisions relate to the so-called first medical indication of a per se already known substance or composition. In other words either a product for use in a method under Article 53(c) EPC is new per se and can constitute the subject-matter of a product claim under Article 53(c), second sentence, EPC, or a product (substance or composition) is already known per se but can nevertheless be granted patent protection provided, under Article 54 (4) EPC, said product has not yet been used in a method under Article 53(c), first sentence, EPC. This first medical indication of a known substance or composition is in general the object of broad generic claims in the form of use-related product claims (Zweckgebundener Stoffanspruch; Revendication de produit pour application ou mise en œuvre). These principles remain unchanged and there can be no dispute in respect of the scope of former Article 54(5) EPC 1973 or current Article 54(4) EPC whose respective wordings are (other than for an editorial amendment) identical.

Article 54 (5) EPC

5.9 In contrast to the absence of any provision on this in the EPC 1973, Article 54(5) EPC now expressly allows further patent protection of substances or compositions already known as medicines provided their use in a method under Article 53(c) EPC be specific and not comprised in the state of the art. Thus, under the new law the lacuna in the former provisions, which had been filled in a praetorian way by the Enlarged Board of Appeal with decision G 5/83 and the case law based on that decision, no longer exists.

5.9.1 However Article 54(5) EPC does not define the nature of the further therapeutic use of a substance or composition already known as a medicine deserving protection under Article 54((5) EPC further than by saying that it must be specific. In particular, it does not define any degree of distinctiveness the new use would be required to have in order to qualify as a specific use within the meaning of that article. On the contrary, the wording of the provision stipulates that "any" specific use not comprised in the state of the art may be eligible for patent protection under that article. In this respect there appear to be two ways of construing said requirement, namely:

- either merely by contrast to the generic broad protection conferred by Article 54 (4) EPC for the first therapeutic application of a known substance or composition, which is then in principle not confined to any particular indication, in which case the second or further claimed use need not necessarily consist in the treatment of a different disease,
- or treating Article 53(c) EPC as the general prohibition and giving the provisions of Article 54(5) EPC only the status of a lex specialis and interpreting this provision narrowly in the sense that only a disease not yet treated by the known substance or composition can constitute a specific use within the meaning of that article.

5.9.1.1 A first reason not to adopt a narrow interpretation of these relevant provisions is that this Board, like any other judicial body, is not under the pretext of construing the law entitled to make on its own motion a distinction where the wording of the law, duly read in its context, makes none (*ubilex non distinguit, nec nos distinguere debemus*). Under this perspective, reading the term "any specific use" as necessarily meaning treatment of another disease would amount to arbitrarily introducing a distinction the law does not make in Article 54(5) EPC, which refers to "any specific use" (emphasis added) in a method of therapy. It would be at odds with the principle of good faith required by Article 31(1) of the Vienna Convention to give the term "any specific use" a limitative meaning contrary to its ordinary one.

5.9.1.2 A second ground not to follow a so-called narrow interpretation of Article 54(5) EPC is that the Vienna Convention nowhere prescribes that recourse need to be had to such a principle. Furthermore, there would be no reason at all in the present referral to have recourse to it since the respective provisions of Articles 53 (c) in fine, 54 (4) and (5) EPC do not constitute exceptions to the absolute prohibition of patenting methods of therapy, but on the contrary rather constitute provisions of the law enjoying an identical ranking and aiming at allowing as a matter of principle patent protection for products, substances or compositions for use in therapeutic methods. To decide the contrary with respect to Article 54(5) EPC would unduly reduce the scope of the new provision of Article 54(5) EPC, and to that extent would not genuinely reflect the intention of the legislator and would be at odds with the hitherto

understanding of Articles 52(4), second sentence and 54(5) EPC 1973.

5.9.2 In fact at an early stage of the preparatory work on the revision of the EPC (see in particular CA/PL 7/99 points 19 and 24-26) it was contemplated to delete Articles 52(4) and 54(5) EPC 1973, now respectively Articles 53(c) and 54(4) EPC. The intended result would then have been that patent protection for the medical methods defined in Article 52(4) EPC 1973 would have been allowed, provided the claimed invention solved a technical problem. On the other hand, if Article 54(5) EPC 1973 would have been removed, substances and compositions claimed as such would have become subject to the usual novelty requirements set forth in paragraphs 1 to 3 of this provision, even for a first medical use, first and further medical uses of the same substance or composition remaining entitled to patent protection if formatted as use claims. However this proposal was soon rejected (see CA/II0/99, page 1, point 1, No. 5). Instead it was contemplated to improve protection for inventions related to the first and second medical uses defined in Article 53(c), first sentence, EPC, of known substances or compositions (see same document CA/II0/99, page 2, point 2, No. 19).

5.9.2.1 This section of the legislative history clearly illustrates the intention of the legislator who considered that the respective concepts of exclusion of therapeutic methods from patentability on the one hand and protection of products to be used in such methods on the other hand, shared the same fate and ranking and therefore could not be either dissociated or mixed up. This also implies that precisely because they are complementary none of these provisions needs to be treated as an exception.

5.9.2.2 Ultimately the revision of the EPC maintained a distinction between first and further medical uses of a known substance or composition reflected in the different wording of the provisions of Articles 54(4) and 54(5) EPC respectively. This indicates beyond any reasonable doubt that the authors of the revision did not adopt the idea of having only equal use-limited protection scope both for the first therapeutic use as well as for any subsequent therapeutic use of a known substance or composition.

5.10 Reformulated the first question corresponds in fact to the following: Is a new use, deserving patent protection, of a per se known medicament, necessarily restricted to a disease not yet treated by said composition? This question was mainly although not unanimously answered in the negative by the Boards of Appeal under the old law, EPC 1973, provided the invention was claimed in the so-called Swiss-type format, adopted by the Enlarged Board of Appeal in its decision G 5/83. That decision of the Enlarged Board of Appeal had filled a gap in the legal provisions and allowed claims concerning a second therapeutic indication of a known product, although not specifying whether such a second use could be something else than the treatment of another disease.

5.10.2 Under the new law, EPC 2000, the lacuna in the old provisions which had been closed in a praetorian

way by decision G 5/83 and the subsequent case law of the boards of appeal, no longer exists. Article 54(5) EPC now provides for patent protection of a known substance or composition for "any specific use" of the said product in a method of therapy provided this use is not comprised in the state of the art and is inventive.

5.10.3 The Enlarged Board comes to the conclusion that there can be only one sensible way of construing the requirement underlying the specificity of the use, namely merely by contrast to the generic broad protection conferred by the first claimed medical application of a substance or composition, which is in principle not confined to a particular indication. Thus, the new use within the meaning of Article 54(5) EPC need not be the treatment of another disease.

5.10.4 This is confirmed by the preparatory documents, which normally witness the intention of the legislator and constitute an ancillary means of interpretation of dispositions of law at least when it comes to their *ratio legis*. In the basic proposal of the revised wording of Article 54 EPC, more precisely in the corresponding explanatory notes established by the Swiss delegation, MR/18/00, point 2, it was explained that in decision G 5/83 "The Enlarged Board of Appeal was asked to decide whether any further medical use could receive patent protection under the EPC (1973) in spite of the wording of Article 54(5) EPC (1973) which seemed to limit patentability to the first medical use. The Enlarged Board of Appeal extended the notional novelty provided for in Article 54(5) EPC 1973 to each further medical use in the so-called 'Swiss type claim', i.e. to a claim "directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application". In document CA/PV 81 e, point 86, the Swiss delegation had already explained the reasoning behind the text (n.b. eventually adopted by the Diplomatic Conference and constituting now Article 54(5) EPC) of its proposal: "... The Swiss delegation's sole concern was to ensure, in the interests of clarity and legal certainty, that existing jurisprudence concerning the first and second medical indications and each further medical indication was anchored in the EPC, making broad protection available for the first medical indication and protection for 'specific uses', if they were not comprised in the state of the art, for second and further indications. For the latter, there was currently no legal basis whatever in the EPC. The EPO proposal was problematic in so far as it said nothing about the extent of protection. The various indications - first, second and further - were therefore conflated, which would lead to changes in case law. Clearly worded legislation was needed to prevent the courts from granting narrow protection for the first medical indication and broad protection for the second indication. The decisive aspect of paragraph 5 of the Swiss proposal was that protection would only be granted for a 'specific use' if it did not yet form part of the state of the art. The aim, therefore, was to provide narrow protection for the second medical indication and broad protection for the first indication. The wording, with 'patentability' and

'specific use' referring to Articles 52 and 69 EPC respectively, did not directly involve novelty. However, these two articles should not be burdened additionally with the 'second medical indication' construct." The explanatory notes MR/18/00, point 4, went on further to confirm this clear intention in that: "The new Article 54(5) EPC eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose-related product protection for each further new medical use of a substance or composition already known as a medicine. This protection is equivalent, as far as the further uses are concerned, to that offered by the 'Swiss type claim'. In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a specific use. This limitation is intended to match as closely as possible the scope of protection to the scope provided by a 'Swiss type claim'." It also appears clearly from the conference proceedings, in particular document MR/24/00, page 71, point 139, that the actual intention of the legislator was "as regards the second or further medical use, (that) the case law evolved by the EPO Enlarged Board of Appeal should be enshrined in the Convention. For the sake of transparency and legal certainty the aim of the basic proposal (in the form of the Swiss proposal) was to keep the legal status quo for medical uses" and further that "The proposed reform (i.e. the adopted text) satisfied the demand users had long been making for the existing loophole in respect of patenting of second and further medical uses to be closed."

5.10.5 From the very wording of decision G 5/83, point 21 of the Reasons, the Enlarged Board of Appeal cannot deduce that said ruling was to be restricted to a new indication in the sense of a new disease. The same holds true for point 23 of the Reasons, reflected in point 2 of the Order of decision G 5/83. Both points mention "a specified new and inventive therapeutic application" which does not necessarily correspond to a new indication being restricted to a "new disease".

5.10.6 This is illustrated by the case law of the Boards of Appeal subsequent to decision G 5/83. In this respect the Enlarged Board of Appeal considers that there is no reason to restrict the intention of the legislator that "the case law evolved by the EPO Enlarged Board of Appeal should be enshrined in the Convention" (see point 5.10.4 above) to the sole teaching of decision G 5/83. In fact the legislator can reasonably be deemed to have been aware of and have wished to include this later jurisprudence; in this respect, the terms "case law evolved" also make more sense.

5.10.7 Under the EPC 1973 a well-established case law already acknowledged patentability of substances and compositions known in the prior art for use in the treatment by therapy of a particular disease, even if they were directed to the treatment of the same illness, provided this treatment was new and inventive.

To cite merely a few see e.g. :

(A)

T 19/86, OJ EPO 1989, 24

T 893/90 of 22 July 1993,

T 233/96 of 4 May 2000,

all relating to a novel group of subjects treated;

(B)

T 51/93 of 8 June 1994,

T 138/95 of 12 October 1999,

both relating to a new route or mode of administration;

(C)

T 290/86, OJ EPO 1992, 414,

T 254/93, OJ EPO 1998, 285,

relating to a different technical effect and leading to a truly new application as set out in T 1020/03, OJ EPO 2007, 204.

5.10.8 The Enlarged Board of Appeal comes to the conclusion that, since the legislator wished to maintain the status quo, as regards the availability of patent protection for further therapeutic uses, and insofar intended no change due to the introduction of the current provisions of Article 54(5) EPC, the principles established by this case law still hold true.

5.10.9 Therefore, the first sentence of Article 53(c) EPC, prohibiting patent protection of methods for treatment by therapy, is to be read and understood together with the provisions of its second sentence and with those of Articles 54(4) and (5) EPC respectively so that far from being mutually exclusive they are complementary. By virtue of a legal fiction Article 54(4) and (5) EPC acknowledges the notional novelty of substances or compositions even when they are as such already comprised in the state of the art, provided they are claimed for a new use in a method which Article 53(c) EPC excludes as such from patent protection. In such cases the notional novelty and following it the non-obviousness, if any, is not derived from the substance or composition as such but from the purpose the claimed substance or composition is related to, namely from its intended therapeutic use. Such use can be either a new indication *stricto sensu* (in the sense of a disease not yet treated by the claimed substance or composition), or one or more steps pertaining by their nature to a therapeutic method which may not be claimed as such. Article 54(5) EPC, however, refers to "any specific use" (emphasis added). On the basis of that wording in conjunction with the declared intention of the legislator to maintain the status quo of protection evolved in the case law of the boards of appeal under decision G 5/83, the Enlarged Board holds that said use cannot be *ex officio* limited to a new indication *stricto sensu*. Thus, decision T 1020/03 (OJ EPO 2007, 204, point 36 of the Reasons) was correct in stating that "... there is a seamless fit, either a method of using a composition is not a treatment by therapy and therefore falls outside the provision of Article 52(4) EPC [1973] first sentence, and so is patentable subject to compliance with the other provisions of the EPC, or else a method is a treatment by therapy and therefore inside the provision of Article 52(4) EPC [1973] first sentence, and so not itself patentable, but use of a composition for making a medicament for use in such treatment by therapy is patentable for unspecified ther-

apy as a first medical indication or for a specified therapy as a further medical indication, again subject to compliance with the other provisions of the EPC, in particular novelty and inventive step."

6 . Answer to the second referred question

6.1 The term "dosage regime" may cover different acceptations that are normally reflected by corresponding features in the wording of the claim. However, the Enlarged Board of Appeal considers that there is no need to define the term more precisely here. Having regard to its findings with respect to the first question and considering in particular that, since Article 54(5) EPC may be used in cases of the treatment of the same illness, the "specific use" in the sense of that provision may reside in something else than the treatment of a different illness, the Enlarged Board of Appeal holds that there is no reason to give to a feature consisting in a new dosage regime of a known medicament a different treatment than the one given to any other specific use acknowledged in the case law (see point 5.10.7).

6.2 Therefore, the second question also has to be answered in the affirmative.

6.3 The Enlarged Board of Appeal does not ignore the concerns with respect to undue prolongations of patent rights potentially resulting from patent protection for claims purporting to derive their novelty and inventive step only from a not hitherto so defined dosage regime for treatment by therapy of an illness already treated by the same drug. Therefore, it is important to stress that, beyond the legal fiction of Article 54(5) EPC, for the assessment of novelty and inventive step of a claim in which the only novel feature would be the dosage regime, the whole body of jurisprudence relating to the assessment of novelty and inventive step generally also applies. In particular, the claimed definition of the dosage regime must therefore not only be verbally different from what was described in the state of the art but also reflect a different technical teaching. Furthermore, assuming for the sake of argument that the claimed modalities of the dosage regime would only consist in a mere selection within the teaching of a broader prior disclosure in the state of the art, then novelty could only be acknowledged if the criteria developed in the jurisprudence of the boards of appeal with respect to selection inventions would be fulfilled. One typical issue in such kinds of cases is whether the dosage regime defined in the claim has been shown to provide a particular technical effect as compared with what was known in the state of the art. In the past, a whole body of jurisprudence has developed concerning the question as to when a technical effect of a claimed therapeutic application not previously described in the state of the art can be recognized as conferring novelty on said application and this jurisprudence continues to be applicable to the assessment of the individual cases under consideration (see in particular T 290/86, OJ EPO 1992, 414; T 1020/03, OJ EPO 2007, 204; T 836/01 of 7 October 2003; T 1074/06 of 9 August 2007). Furthermore, if the distinguishing feature of a claim seeking patent protection for a known medicament to be used for a different treatment of the same

illness is a dosage regime and is something else than a mere selection from a prior broader disclosure, a new technical effect caused by said feature shall be considered when examining inventive step under Article 56 EPC.

6.4 The question of dosage regimes has also been the object of decisions of courts of EPC Contracting States. In the United Kingdom, the Court of Appeal for England and Wales reached the same result as here (Decision of 21 May 2008 in re Actavis UK Limited v. Merck & Co. Inc., (2008) EWCA Civ. 444). In Switzerland, the Tribunal of Commerce of the Canton of Zurich ruled in the opposite direction (Decisions of 14 April 2009, AA 090075 and AA 090077). In Germany, the Federal Court of Justice had doubts with respect to a claim worded similarly to the one in suit here, but none with respect to a claim in which the substance used was prepared ("hergerichtet") for administration according to a given dosage regime (Decision of 19 December 2006, X ZR 236/01 "Carvedilol II", Reasons II.1 and III.1).

The patents underlying these decisions were under the ambit of the old law which did not contain any notional acknowledgement of novelty of a claim directed to a known product based on a feature relating to an intended further - therapeutic - use of that product. The new provisions of Article 54(5) EPC were precisely intended to fill this lacuna. 6.5 In respect of second and further medical indications the EPC now allows use-related product claims directed to the substance itself whereas under EPC 1973 decision G 5/83 allowed claims directed to the use of a substance for the manufacture of the drug for a therapeutic indication ("Swiss-type claims"). It appears that the rights conferred on the patentee by the claim category under Article 54(5) EPC are likely broader, and could, in particular, lead to possible restrictions on the freedom of medical practitioners to prescribe or administer generics. However, in view of the clear provisions of Articles 53 (c), second sentence, and 54(5) EPC and the intention of the legislator, the Enlarged Board has no power to broaden or reduce in a praetorian way the scope of these provisions. If deemed necessary, the freedom of medical practitioners may be protected by other means on the national level (see also [G 1/04](#), points 6.1 and 6.3 of the Reasons).

Answer to the third question

7.1 Consequence of the new law in respect of so called Swiss-type claims

7.1.1 Claim 1 submitted to the referring Board of Appeal for consideration is drafted in the so-called Swiss-type format. It has been established practice under the EPC 1973 that a patent related to a further medical application of a known medicament could only be granted for a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified therapeutic application (cf. G 5/83, point 2 of the Order). Since the medicament per se was not new the subjectmatter of such a claim was rendered novel by its new therapeutic application (cf. G 5/83, points 20 and 21 of the Reasons). This praetorian approach was a

"special approach to the derivation of novelty" (cf. point 21 of G 5/83) and therefore constituted a narrow exception to the principles governing the novelty requirements which was not intended to be applied in other fields of technology. That praetorian ruling found its cause in the fact that a claim directed to the use of the substance or composition for the treatment of the human body by therapy had to be regarded as a step of treatment (see point 18, in fine of G 5/83). A claim of that kind was forbidden. On the other hand only the first medical indication of a known composition in the form of a medicament was by virtue of Article 54(5) EPC 1973 (Article 54(4) EPC 2000) entitled to be drafted in the form of a purpose-related product claim. And since the intention of the legislator was clearly not to exclude second therapeutic indications of a known medicament from the field of patentability the so-called Swiss-type claim constituted the adequate but exceptional solution.

7.1.2 Article 54(5) EPC now permits purpose-related product protection for any further specific use of a known medicament in a method of therapy. Therefore, as mentioned in the preparatory document (MR/24/00, point 139) the loophole existing in the provisions of the EPC 1973 was closed.

In other words "cessanteratione legis , cessat et ipsa lex " , when the reason of the law ceases, the law itself ceases.

The cause of the praetorian approach ceasing, the effect must cease. As stated in decision T 406/06 of 16 January 2008, point 5 of the Reasons:

"The question arises whether the exception to the general novelty requirement, which was accepted in decision G 5/83 under the EPC 1973, is still justified under the new legal framework which enables the applicant to frame its claims in accordance with the provision of Article 54 (5) EPC 2000 in order to obtain patent protection for a new therapeutic application of a known medicament."

7.1.3 Moreover, Swiss-type claims could be (and have been) considered objectionable as regards the question as to whether they fulfill the patentability requirements, due to the absence of any functional relationship of the features (belonging to therapy) conferring novelty and inventiveness, if any, and the claimed manufacturing process. Therefore, where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83.

7.1.4 The Enlarged Board of Appeal is aware of the fact that patents have been granted and many applications are still pending seeking patent protection for claims of this type. In order to ensure legal certainty and to protect legitimate interests of applicants, the abolition of this possibility by the interpretation of the new law given by the Enlarged Board in this decision shall therefore have no retroactive effect, and an appropriate time limit of three months after publication of the present decision in the Official Journal of the EPO is set in order for future applications to comply with this

new situation. In this respect the relevant date for future applications is their date of filing or, if priority has been claimed, their priority date.

Other procedural matters

The appellant has filed new requests in the course of the present proceedings. However since the Enlarged Board has no competence to decide on the subjectmatter of the appeal underlying the referral it will be for the referring Board of Appeal to decide on their admissibility or their merits.

Order

For these reasons it is decided that:

The questions referred to the Enlarged Board of Appeal are answered as follows:

Question 1:

Where it is already known to use a medicament to treat an illness, Article 54 (5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.

Question 2:

Such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.

Question 3:

Where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83. A time-limit of three months after publication of the present decision in the Official Journal of the European Patent Office is set in order that future applicants comply with this new situation.
